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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,221	02/16/2001	Doris Hubler	JENA 3	7076

23599 7590 08/19/2003

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/19/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/719221

Applicant(s)

HUBLER

Examiner

WFBMAN

Group/Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 5/15/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1-1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-5, 7-28 is/are pending in the application.
- Of the above claim(s) 7-11, 18, 19, 21-28 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-4, 12-17, 20 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 12-17, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hesch et al in view of Horrobin, Shibutani et al and Riley et al.

Hesch et al. Disclose that it is well-known in the art that androgens such as testosterone are useful in methods of treating androgen deficiency in man (column 1, lines 10-16). Such a deficiency is known to cause benign enlargements of the prostate (column 1, lines 46-54). Testosterone propionate is specified (column 1 line 13).

Hesch et al. do not disclose gestagens.

Horrobin teaches that those with benign prostatic hypertrophy are at risk of developing prostatic cancer (column 40 lines 21-27).

Shibutani et al teach treatment and prevention of prostate cancer with dienogest column 3 lines 52-56, column 2 lines 31-32.

It would have been obvious to one of ordinary skill to add dienogest to the androgen deficiency treatment disclosed by Hesch et al to achieve the beneficial effect of preventing prostate cancer in view of Shibutani et al in light of the fact that androgen deficiency can give rise to prostatic hypertrophy in view of Hesch et al which in turn can lead to prostate cancer in view of Horrobin.

As to the claimed ranges of androgens and gestagens dosages, it is within the skill in the art to select optimal parameters such as ratios, ranges of doses or weight

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percents of components in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 19880). Therefore, the ratios, ranges of doses or weight percents instantly claimed are not considered critical absent evidence showing unexpected and superior results.

As to the claimed dosage forms of androgens and gestagens, Riley et al. disclose varieties of dosage forms for androgens and gestagens. It would have been obvious to one having ordinary skill in the art to choose a particular dosage form appropriate for the patient under treatment.

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Applicants have seized upon the language previously cited in claim 8 in Shibutani et al, which discloses prevention of a recurrence of cancer. However, the teaching in the patent is broader than claim 8, teaching a prevention of prostate cancer not limited to preventing a recurrence, as now cited above in the discussion of shibutani et al.

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 308-4432. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 305-3592 for regular communications and 305-1235 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234.

Webman/tgd  
July 31, 2003

  
EDWARD J. WEBMAN  
PATENT EXAMINER  
6-30-03